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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,683	04/07/2000	Antonius Arnoldus Christiaan Jacobs	99471 US	1432

7590 07/22/2002
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Patent Department
Intervet Inc
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Millsboro, DE 19966

EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/22/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/544,683

Applicant(s)
Jacobs et al

Examiner
Portner

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1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 10, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9, 10, and 12-17 is/are pending in the application.
- 4a) Of the above, claim(s) 4-7, 10, and 12-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-7, 9, 10, and 12-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

DETAILED ACTION

Claims 1-7, 9-10, 12-14¹⁵⁻¹⁷ are pending.

Claims 4-7, 10, 12-14¹⁵⁻¹⁷ are withdrawn.

Claims 1-3 and 9 have been amended and are under consideration.

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 10, 2002 has been entered.

Rejections Withdrawn

1. Claims 1-2 rejected under 35 U.S.C. 102(b) as being anticipated by Dolby et al (1986), in light of the amendment to recite the presence of surface antigens of 13+/- 3kD, 60+/- 5 kD and 97+/- 5kD for which the Dolby et al reference is silent .
2. Claim 9 rejected under 35 U.S.C. 102(b) as being anticipated by Kervella et al (August 1993), in light of the amendment to recite the presence of surface antigens of 13+/- 3kD, 60+/- 5 kD and 97+/- 5kD for which the Kervella et al reference is silent .

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Rejections Maintained

3. Claim 3 rejected under 35 U.S.C. 112, second paragraph which recites the term "R2", for reasons of record in paper number 6.
4. Claims 1-2 and 9 rejected under 35 U.S.C. 102(b) as being anticipated by Blaser et al (1986) , for reasons of record in paper number 6, paragraph 10.
5. Claims 1-3 and 9 rejected under 35 U.S.C. 102(b) as being anticipated by Cawthraw et al (1994), as previously applied to claims 1-3, for reasons of record in paper number 6, paragraph 12.

Response to Arguments

6. Applicant's arguments filed July 10, 2002 have been fully considered but they are not persuasive.
7. Applicant responded to the rejection of claim 3 under 35 U.S.C. 112, second paragraph which recites the term "R2", by stating that "R2" is a well known descriptor for a flagellaless strain of Campylobacter, states that the claim is enabled, refers to published articles that utilize the strain and concludes that the term "R2" is not an arbitrary term.
8. It is the position of the examiner, while the specification provides original descriptive support for the term "R2", it is not clear what characteristics this strain has that other flagellaless strains do not have, especially from the narrative found at page 3, lines 23-29. The meaning of this term is not distinctly claimed, because how this strain further limits the composition of antibodies

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produced, relative to any other flagellaless strains of *Campylobacter jejuni* (claim 2 from which claim 3 depends) was not clear from the narrative at page 3, lines 23-29 of the specification.

While the claim recites a strain name, R2, how this strain would result in a materially different composition for induction of antibodies is not distinctly claimed. If strain "R2" has distinct characteristics from other flagellaless *C.jejuni* strains that could only be found in this strain, what are these characteristics? What distinguishing characteristics does the "R2" strain have that other *Campylobacter jejuni* strains do not have? How does claim 3 clearly define what characteristics would result in a materially different vaccine composition from any other flagellless strain of *C.jejuni*? Clarification of the claimed invention of claim 3 is requested.

9. The rejection of claims 1-2 and 9 under 35 U.S.C. 102(b) as being anticipated by Blaser et al (1986) is asserted to have been obviated through amendment of the claims to recite "effective amount".

10. It is the position of the examiner that the effective amount is any amount that is effective to immunoreact with a flagellaless *Campylobacter* strain. The amount of antibodies to be effective against a single pathogenic cell would differ from the amount that is effective against a disease causing number of *Campylobacter jejuni* bacteria for a chicken or human. Blaser et al does disclose an antisera obtained (see page 50, line 1) through immunization with the flagellaless strain of *Campylobacter jejuni* and the strain comprised antigens of about 97 kDa (see Figure 1, pages 48), antibodies to a 63 kDa antigen were induced (see page 49, col. 2, paragraph 2, last

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sentence; and antibodies to an antigen of about 13 kDa is see in the Western blot of Figure 4, page 50, col. 1, top of page). By all comparable data, the antiserum comprised the now claimed antibodies. The rejection is maintained for reasons of record in paper number 10.

11. The rejection of claims 1-3 and 9 under 35 U.S.C. 102(b), as previously applied to claims 1-3, as being anticipated by Cawthraw et al (1994) is argued that Cawthraw does not disclose, teach or suggest a vaccine that comprises an effective amount of antiserum raised against a flagellaless *Campylobacter* strain.

12. It is the position of the examiner that Cawthraw et al disclose anti-*C.jejuni* IgG antibodies induced to a strain of *Campylobacter jejuni* referred to as R2, a flagellaless strain of *Campylobacter jejuni*, wherein the antibodies were administered to eggs and ultimately to young chickens (see page 344, col. 2, second paragraph). The antiserum containing antibodies was passively administered to young chicks, wherein antibodies were found in uninfected 1 week old birds, which indicates passive protection afforded to the chick by the antibodies (see page 347, col. 1, last paragraph). The isolated composition of antiserum containing antibodies induced to *C.jejuni* R2 functioned as an effective vaccine to protect the next generation of chicks (Figure 2, page 345). The purified antibodies raised to *C.jejuni* R2 represents a composition of antibodies that was shown to function as a vaccine.

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The strain induced antibodies to a 62 kDa protein (Cawthraw et al ,abstract), the Western blot Frame 6 of Figure 3, page 346, shows antibodies to an about 13 kD antigen and to antigens of great relative molecular weight than 60 kDa, and would be of about 92 kDa.

The stain "R2" of the prior art appears to be the same or equivalent strain of the instantly claimed invention used to induce antibodies, wherein the antibodies of the prior art were isolated (See page 344, col. 2, paragraph 2) and the antibodies are taught to be useful for passive immunization of chickens (see page 348, col. 1, paragraph 1).

The reference inherently anticipates the instantly claimed invention for reasons of record in paper number 10.

New Claim Limitations/New Grounds of Rejection

Claim Rejections - 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to recite the phrase "wherein the flagellaless *Campylobacter* strain recognizes a 97 kD"... "band on a Western Blot". How can a strain of bacteria recognize a

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band on a Western Blot? The claim could be made clear by amendment to recite either that the antibodies immunoreact with an antigen of the flagellaless strain in a Western blot or the strain -- comprises-- a 97 kD protein that is visualized in a Western blot through specific binding of the antibodies to the protein in a Western Blot. Clarification of how the strain recognizes the band is requested.

Conclusion

15. This is a non-final action.

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

17. US Pat. 5,871,731 is cited to show a method that detects antibodies directed against *Campylobacter jejuni* (see claim 4).

18. US Pat. 6,077,678 is cited to show a kit that comprises antibodies to *Campylobacter* bacteria (see claim 15).

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703)

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308-4242. The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196

VGP

July 17, 2002


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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